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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,724	12/08/2003	Antonius Arnoldus Christiaan Jacobs	I 1999.452 US C1	5481

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Intervet/Schering-Plough Animal Health
PATENT DEPARTMENT
PO BOX 318
29160 Intervet Lane
MILLSBORO, DE 19966-0318

EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
02/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,724	JACOBS ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/25/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11,13-16 and 20-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11,13-16 and 20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 09/25/08 has been acknowledged and fully considered. *Claims 9-11, 13-16 and 20-28 are pending and are examined in this office action.*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Claim Rejections - 35 USC § 112

Claims *9-11, 13-16 and 20-28* are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for protecting a mammal against *Streptococcus equi* infection by submucosal injection of a live attenuated *Streptococcus equi* strain (TW980), does not reasonably provide enablement for a method for protecting a mammal against all bacterial infection by sub mucosal injection of any live bacterial vaccines as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reason of record as set forth in the office action mailed on 06/25/08.

Response to Argument (enablement)

The applicant argues that the ordinary practitioner knows well that he can select from any number of available live attenuated bacterial vaccines. That is well within the skill of the art and it is not required for Applicants to teach the preparation of live attenuated bacterial vaccines as they are readily available. What was not known, and this is taught by Applicants, is a method for avoiding adverse reactions at the injection site of live vaccines, which result in unsightly lesions and, in the case of food animals, create a recognized significant problem in lost meat value. It had not previously been recognized that such adverse reactions could be reduced, short lived, or avoided by

administering the vaccine submucosally rather than subcutaneously or intramuscularly. The applicant argues that although it may be correct that the efficacy of an attenuated bacterial vaccine cannot be absolutely predicted, as noted above, attenuated bacterial vaccines are not the invention presently claimed. It is the use of known vaccines in methods by which expected adverse reactions are now avoided.

However the applicant's arguments are found not persuasive. Even though applicant asserts that in view number of available live attenuated bacterial vaccines invention as claimed is fully enabled, the argument has been found not fully persuasive because the scope of invention as claimed is much broader than the limited number of vaccines available at the time the instant application was filed. Furthermore each vaccine is host specific, whereas the scope of invention as claimed encompasses the use of any live bacterial attenuated vaccine for any mammal.

The earlier office action has provided clear evidence that the efficacy of vaccine could be best judged in the context of pathogen/host etiology (see Curtiss R. J. Clin. Invest. 110(8):1061-1066, 2002, that explain unpredictability associated with the use of test candidate vaccines in mice or guinea pigs that probably will not be reflective of responses in humans).

Furthermore, impossibility of determining, from reading of specification and record, number of mutant strains of original S. typhi and hyperconjugant strains of genetically engineered hybrid that are originally formed in each experiment, nor what amount of time, effort, and level of skill is needed to isolate single strains which can then be cloned to yield useful vaccines, supports conclusion that practice of invention would require undue experimentation. Ex parte Formal, et al., 230 USPQ 546 (Bd. Pat. App. & Int. 1986)

The USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of skill.

Even description of several newly discovered strains of bacteria having one particularly desirable metabolic property in terms of conventionally measured culture characteristics and number of metabolic and physiological properties does not enable one of ordinary skill in relevant art to independently discover additional strains having same specific, desirable metabolic property, i.e., production of particular antibiotic; in other words, verbal description of new species does not enable one of ordinary skill in relevant art to obtain strains of that species over and above specific strains made available through deposit in recognized culture depositor. Ex parte Jackson, Theriault, Sinclair, Fager, and Karwowski, 217 USPQ 804 (Bd. Pat. App. & Int. 1982)

Furthermore, determination of what constitutes undue experimentation in given case requires application of standard of reasonableness, having due regard for nature of invention and state of art; test is not merely quantitative, since considerable amount of experimentation is permissible, if it is merely routine, or if specification in question provides reasonable amount of guidance with respect to direction in which experimentation should proceed to enable determination of how to practice desired embodiment of invention claimed. Ex parte Jackson, Theriault, Sinclair, Fager, and Karwowski, 217 USPQ 804 (Bd. Pat. App. & Int. 1982). In the instant case the applicants disclosure is only limed to Strep equi (TW928) see example-1. The example 2 and 3 (Spec. pages 8-9) are only limited to wild-type bacterial strains of Strep. zooepidemicus and Actinomyces pyogenes, which doses not constitute a live attenuated bacterial vaccine (capable of providing immune protection and not infection).

Since the submucosal injection of any live attenuated bacterial strain as vaccine is not considered routine in the art and without sufficient guidance to a specific bacterial strain and vaccination outcome base upon the immune protection the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir,1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have

to engage in excessive and undue amount of experimentation to exercise the invention as claimed.

Claims 9-11, 13-16 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new mater). The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9, as amended recites new claim limitation "**replicate at the injection site**". However a careful review by the examiner of the specification failed to identify any support for this new limitation. Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter. As MPEP 2163.06 notes "If **new matter** is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sumesh Kaushal/
Primary Examiner, Art Unit 1633

Sumesh Kaushal
Primary Examiner
Art Unit 1633